UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

KEVIN VILLARE, individually and on behalf of all others similarly situated,

– against –

Plaintiff,

ABIOMED, INC., MICHAEL R. MINOGUE, and TODD A. TRAPP,

Defendants.

OPINION & ORDER

19 Civ. 7319 (ER)

RAMOS, D.J.:

Lead Plaintiff Local 705 International Brotherhood of Teamsters Pension Fund ("Local 705") brings this federal securities class action against Abiomed, Inc. ("Abiomed"), Michael R. Minogue, and Todd A. Trapp. In its Amended Complaint, Local 705 seeks to pursue remedies under sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5, promulgated thereunder. Doc. 52. Local 705 brings its claims on behalf of purchasers of publicly traded securities of Abiomed between May 3, 2018 to July 31, 2019 (the "Class Period").

Pending before the Court is Defendants' motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). Doc. 56. For the following reasons, Defendants' motion is GRANTED.

I. BACKGROUND

A. Factual Background

The following facts are taken from the Amended Complaint or SEC filings referenced in the pleading, and are assumed to be true for purposes of the instant motion. *See Hesse v. Godiva Chocolatier, Inc.*, 463 F. Supp. 3d 453, 462 (S.D.N.Y. 2020).

1. The Parties

Founded in 1981, Abiomed develops, manufactures, and markets devices that are designed to improve blood flow to the coronary arteries and to temporarily assist the pumping function of the heart. Doc. 52 ¶ 37. Minogue served as Abiomed's chairman, president, and CEO at all relevant times. *Id.* ¶ 33. Trapp served as Abiomed's vice president and chief financial officer at all relevant times. *Id.* ¶ 35. Minogue and Trapp signed Abiomed's annual reports and Sarbanes-Oxley Act certifications and participated in each of the company's quarterly-earnings conference calls. *Id.* ¶ 34–35. Local 705 and the other plaintiffs purchased or otherwise acquired Abiomed securities during the Class Period. *Id.* ¶ 31.

2. Abiomed's Impella Products and Its Competition

The strategic focus and driver of Abiomed's revenue growth is its family of the Impella Platform, which includes the Impella 2.5, Impella 5.0, Impella LD, Impella CP, and Impella RP. *Id.* ¶¶ 38–39. The Impella products (the "Impella Pumps") are percutaneous heart pumps—that is, they are installed by puncturing the skin with a needle rather than by surgical means—with some pumps used by interventional cardiologists in the cath lab, some used by cardiac surgeons, and some used by both. *See id.* ¶¶ 42–45. The Food and Drug Administration ("FDA") categorizes these devices as Class III devices, meaning that they require premarket approval for sale to the public, based on a determination by the FDA that a given device is safe and effective for its intended use. *Id.* ¶ 41. During the Class Period, sales of Impella Pumps accounted for 96% of Abiomed's total revenue, and Minogue and Trap stressed the importance of these products. *Id.* ¶¶ 38, 207–10.

Although many of the Impella Pumps had been on the market since 2012, Abiomed began to show substantial year-on-year revenue growth after the FDA granted the Impella RP a humanitarian exemption in the third quarter of Fiscal Year 2015.

1 Id. ¶

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¹ A device that is so designated is exempt from the effectiveness requirements imposed by the FDA, but is subject to certain profit and use restrictions. Doc. 52 ¶ 39 n.10.

39. The Impella RP, unlike the other Impella Pumps, is designed to compensate for right heart failure, and was touted as the "first percutaneous single access heart pump designed for right heart support to receive FDA approval." *Id.* ¶ 45. As Local 705 notes, Abiomed reported year-on-year revenue growth of 34% for the third quarter of 2015 and went on to report year-on-year revenue growth of more than 25% for the next fifteen quarters. *Id.* ¶¶ 40, 54.

Intra-Aortic Balloon Pump ("IABP") therapy represented the biggest competition for the Impella Pumps. *Id.* ¶ 46 & n.14. IABP is a therapeutic device that helps the heart pump more blood. *Id.* ¶ 46. It consists of a long balloon attached to the end of a catheter, is inserted through the skin and into the aorta, and is attached to a computer console that inflates and deflates the balloon as the heart beats. *Id.* According to Local 705, IABP has been the most widely used mechanical circulatory support device for decades. *Id.* ¶ 47.

3. Abiomed's Five-Year Vision for Growth and Financial Revenue Outlook

On August 11, 2015, during its annual investor conference, Abiomed laid out its long range earnings plan, which included specific figures for revenue and operating margin goals. *Id.* ¶ 50. Minogue and other Abiomed executives informed investors that, by August 2020, Abiomed expected annual Impella Pump revenues in the range of \$1.2 and \$1.8 billion, while also growing the company's operating margin to more than 30%. *Id.* ¶¶ 50–51. Abiomed based these projections on three factors: (1) assumptions about the size of the available market for the Impella Pumps, (2) the average selling price of the pumps, and (3) the financial impact of unlocking new patient opportunities. *Id.* ¶ 50.

During the presentation, Minogue informed investors that the potential market for Impella Pumps included 221,000 patients, with potential sales revenue of more than \$5 billion. *Id.* ¶ 51. Abiomed stated that, based on the company's current growth, the company would have 21.5% market penetration by Fiscal Year 2020. *Id.* According to Local 705, several analyst reports responded favorably to this presentation, while

acknowledging the need to dedicate meaningful resources to the expansion of Abiomed's products. *See id.* ¶¶ 52–53.

4. Abiomed's Public Statements During the Class Period

On May 3, 2018, Abiomed issued a press release, attached to a Form 8-K, reporting the company's financial results for its fourth fiscal quarter and full year, ending on March 31, 2018. *Id.* ¶ 125. The press release reported quarterly revenue of \$174 million, up 40% year over year, and yearly revenue of \$594 million, up 33% year over year. *Id.* That same day, Abiomed hosted a conference call to discuss the content of the press release. During the call, Minogue stated:

And we're also maintaining this best growth rate at a higher base and we're doing it while improving operating margin. So again, it's sustainable growth[,] it's strategic, but we have to continue to improve outcomes and go at the right pace to have that—the success we want, which is to achieve the best outcomes for patients.

Id. ¶ 126.² Regarding Abiomed's revenue projections, Trapp stated the following:

The guidance is based on the following assumptions: continued penetration of the existing and expanded markets for Protected [Percutaneous Coronary Intervention] in cardiogenic shock; accelerated growth in Impella RP post-[pre-market] approval and approximately \$10 million in revenue from Japan. The business continues to expand rapidly, and our growth rates are in line with our 5-year vision outlined back in 2015. We will continue with our patients-first sustainable growth model.

Id. ¶ 127.

Minogue also touted the increased adoption of the Impella RP line, stating:

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² Unless otherwise noted, all emphases in quotations from the Amended Complaint have been omitted.

Impella RP also delivered solid results in our second full quarter since the commercial launch with 48 new U.S. sites and growth of 93% in patients and 154% in revenue. However, Impella adoption is a function of training, data and time. And as a result, we are still in the early innings with a penetration rate of approximately 9% of 231,000 patients in the U.S. alone.

. . .

From a [Center for Medicare and Medicaid Services] population perspective, most patients above 65 years old are not candidates for heart transplant and prioritize heart recovery above all other treatment options based on quality of life and cost. We believe our continued focus on best practice protocols are driving improved clinical outcomes and adoption.

. . .

In the [Impella] RP we're only 19% penetrated in the install base. So we have essentially, many years ahead of new doctors, new indications and new products into all the existing U.S. hospitals in our current install base.

Id. ¶ 128. Trapp also touted the expanded use of Impella Pumps—and the Impella RP specifically—stating:

"Both the [Impella] 5.0 and RP are now being adopted by more sites and have significant runway. . . . We saw broadbased growth in the U.S. and outside the U.S. due to continued adoption of the entire Impella platform. . . . We are replacing technology that's been around for 40 years, and we're going for the global standard of care.

Id. ¶ 129. Additionally, Minogue highlighted the expanded approval by the FDA of the Impella Pumps, stating: "While we remain focused on the 231,000 U.S. high-risk patient

population, we acknowledge that these additional indications expand our addressable market and enable a wider range of patients in the future." *Id.* ¶ 130.

In response to these statements, analyst reports noted Abiomed's strong growth, and expressed optimism about continued growth for the company. *See id.* ¶¶ 131–33.

On May 24, 2018, Abiomed filed its annual report on Form 10-K with the Securities and Exchange Commission ("SEC"), reporting the company's financial and operating results for the fourth fiscal quarter and full year 2018. *Id.* ¶ 134. Minogue and Trapp certified this filing, which stated: "Our strategic focus and the driver of our revenue growth is the market penetration of our family of Impella heart pumps." *Id.* ¶¶ 134-35.

On July 26, 2018, Abiomed issued a press release, attached to a Form 8-K signed by Trapp, reporting the company's financial results for the first fiscal quarter of 2019—which ended on June 30, 2018—and reporting revenue of \$132.5 million, up 36% year over year. *Id.* ¶ 137. In the release, Minogue stated: "Abiomed is committed to sustainable growth and improving patient outcomes each quarter. We do this through advanced training, product enhancements and sharing of best practices derived from real world experience." *Id.*

That same day, Abiomed hosted a conference call to discuss these financial results. *Id.* ¶ 138. During this call, Minogue touted that Impella RP devices were now being used at 320 sites, and that the company expected to see continued demand for the Impella 5.0 and RP in the coming quarters. *Id.* Regarding the Impella RP, Minogue stressed that "we are in more of a full launch mode. We're continuing now to add 40 to 50 centers a quarter. We are learning things about the product itself, but remember it has multiple types of patients." *Id.* Minogue also emphasized the company's growth, stating:

In Q1, we delivered another record in revenue of \$180 million, up 36% versus prior year. U.S. patient utilization increased by 30% and was driven by Impella adoption in the

Protected [Percutaneous Coronary Intervention] and cardiogenic shock indications, which grew 24% and 37%, respectively.

. . .

We have maintained our disciplined execution on our strategic goals and increased manufacturing capacity while expanding Impella adoption with new products, new indications, and new geographies.

. . .

We believe our focus and investment on training will translate to increased Impella adoption and improved patient outcomes.

. . .

However, we're still in the early stages of educating and training everyone on these new indications, and we do expect to see more of these patients to continue to grow for the next couple of years.

Id. ¶ 139. Similarly, Trapp touted Abiomed's revenue growth and the expansion of the Impella Pumps, stating: "Our platform of Impella products gives us the ability to make efficient investments in technology, which will lay the groundwork for improving clinical outcomes and sustaining long-term growth." *Id.* ¶ 140.

In response to these statements, several analysts expressed optimism about Abiomed's potential for growth. *Id.* ¶ 141–42. On August 2, 2018, Abiomed filed its quarterly report on Form 10-Q with the SEC, reporting the company's financial and operating results for its first fiscal quarter of 2019. *Id.* ¶ 143. Trapp signed the form, and along with Minogue certified the filing. *Id.*

On November 1, 2018, Abiomed issued a press release, attached to a Form 8-K signed by Trapp, announcing its financial and operating results for its second quarter of

Fiscal Year 2019—which ended September 30, 2018. *Id.* ¶ 145. The press release reported quarterly revenue of \$181.8 million, an increase of 37% year over year. *Id.*

That same day, Abiomed hosted a conference call to discuss these results. *Id.* ¶ 146. During the call, Minogue stated: "Abiomed is positioned for sustainable growth and building the field of heart recovery with disciplined execution." *Id.* Minogue again emphasized that Abiomed was successfully "executing [its] plan for sustainable growth." *Id.* Minogue also noted the expansion of the Impella Pumps, stating: "We are confident in our future with Impella growth opportunities of several hundred thousand patients, with new and existing indications, new products and new geographies." *Id.* ¶ 147. Minogue also emphasized that Abiomed believed it would "get 100% of [the] 231,000 patients" it had identified as its possible market for Abiomed Pumps. *Id.* Additionally, Minogue stated that the Impella RP was enjoying substantial demand, and stressed Abiomed's commitment to training and protocols. *Id.* ¶ 149.

Trapp also commented on the company's potential growth:

We will continue to make these growth investments as we are still in the early stages of market penetration in our top 3 targeted countries of the U.S., Germany and Japan.

. . .

We are well positioned to deliver our plan for 2019 and beyond.

. . .

So again, we'll continue to grow at a pace that we think is sustainable, and our goal is to remain one of the fastest-growing, most profitable medtech companies in the market.

Id. ¶ 148.

In response to these statements, several analysts again expressed optimism about Abiomed's potential for growth. *See id.* ¶¶ 150–51. On November 6, 2018, Abiomed filed its quarterly report on Form 10-Q with the SEC, reporting the company's financial and operating results for its second fiscal quarter of 2019. *Id.* ¶ 152. Trapp signed the form, and along with Minogue certified the filing. *Id.*

On January 31, 2019, Abiomed issued a press release, attached to a Form 8-K signed by Trapp, reporting Abiomed's financial and operating results for the third quarter of Fiscal Year 2019—which ended December 31, 2018. *Id.* ¶ 155. According to the press release, the year-over-year quarterly growth rate dropped from the previous quarter, from 37% to 30%. *Id.* The press release also touted the company's record revenue, with Minogue stating: "We remain focused on disciplined execution and sustainable growth so that even more patients around the world can benefit from heart recovery." *Id.*

That same day, Abiomed hosted a conference call to discuss the quarterly results from the press release. *Id.* ¶ 156. During the call, Minogue stated that Abiomed was "investing in the commercial distribution to prepare for the expansion of products in the short and midterm, such as Impella CP, Impella Connect, Impella 5.5 and Impella RP." *Id.* Trapp, commenting on the company's target for its operating margin, stated: "Keep in mind that the 30% was our 5-year operating margin target that we communicated 3.5 years ago. So we're ahead of that projection, and we will continue to drive for best-inclass performance." *Id.* ¶ 157. Additionally, Trapp commented that "we're going to continue to grow at a pace that we think is sustainable with a focus on patient outcomes. And again . . . our goal remains to be one of the fastest-growing, most profitable medtech companies in the market." *Id.*

In response to these statements, analysts again expressed optimism about the sustainability of Abiomed's growth. *See id.* ¶¶ 158–59. On February 5, 2019, Abiomed filed its quarterly report on Form 10-Q with the SEC, reporting the company's financial

and operating results for its third fiscal quarter of 2019. *Id.* ¶ 160. Minogue and Trapp certified the filing. Id.

5. FDA Letter

On February 4, 2019, the FDA issued a letter to health care providers concerning the data from Abiomed's pre-market clinical studies. *Id.* ¶ 60. According to that letter, in those studies—where strict inclusion and exclusion criteria were followed—73.3% of patients survived to 30 days after the removal of the device or after hospital discharge, whichever period was longer. *Id.* In a separate, post-approval study, however, only 17.4% survived to that same endpoint. *Id.* According to the FDA, the patients in the latter study were more likely than the patients in the former to have been in cardiogenic shock for longer than forty-eight hours, to have experienced in-hospital cardiac arrest, to have been treated with an intra-aortic balloon bump, or to have suffered a pre-implant hypoxic or ischemic neurological event. *Id.* Accordingly, the FDA advised that "physicians should be aware that the occurrence of one or more of these events prior to Impella RP implantation may decrease expected survival rate." *Id.*

6. Slow Down in Abiomed's Growth

Abiomed's next few fiscal reports showed a slowdown in the company's growth rate. On May 2, 2019, Abiomed issued a press release, attached to a Form 8-K signed by Trapp, reporting the company's financial and operating results for the fourth quarter and full Fiscal Year 2019—both of which ended on March 31, 2019. *Id.* ¶ 163. The press release reported revenue that was \$10 million short of analyst expectations, and which had increased only 19% year over year. *Id.* ¶ 164. In the press release, Minogue acknowledged the disappointing results, stating: "Q4 did not meet our expectations. I take full responsibility for our disappointing performance given a soft March." *Id.* Still, Minogue also stated that Abiomed "had already initiated a plan of action to correct the course," and that he was "confident in our innovation and business today as well as long-term outlook for Abiomed." *Id.* The press release also stated: "The company is giving its

fiscal year 2020 guidance for total revenues to be in the range of \$900 million to \$945 million, an increase of 17% to 23% over the prior year." *Id.* ¶ 165.

That same day, Abiomed hosted a conference call to discuss its quarterly results. *Id.* ¶ 166. Minogue reiterated the figures from the press release, and emphasized that he planned on discussing changes and a plan of action that Abiomed "[had] already initiated to correct the course." *Id.* Minogue further emphasized that "Abiomed has a long and proven track record of execution, posting over 20% in organic revenue growth for 18 consecutive quarters," "while significantly expanding full year operating margins from 12.5% to 29.2%." *Id.* He also stated: "We remain confident in our business and our short to long-term outlook. We're confirming that our investment thesis remains fully intact." *Id.* Minogue then proceeded to discuss "lessons learned" from the quarter, stating that Abiomed believed the slowdown "occurred as a result of customer confusion stemming from the February 4 FDA letter to health care providers," "coupled with our response to prioritize Impella RP… which unintentionally distracted our focus away" from other initiatives. *Id.* Further, according to Minogue, "competitive companies likely capitalized on the confusion with our customers." *Id.*

From there, Minogue outlined changes Abiomed had implemented to address the disappointing quarterly performance. *Id.* Additionally, he specified steps that Abiomed believed would "eliminate noise and highlight the clinical benefits of the Impella Pumps for both interventional cardiologists and the heart failure community, which includes heart surgeons." *Id.* Despite all these efforts, Minogue stated that "it will likely require at least a quarter of execution to eliminate all confusion on the Impella platform." *Id.* Nevertheless, Minogue emphasized, "our U.S. April growth rate showed improvement over March, but it is not yet where we want it to be. We will rise up. . . . We have more work to do to educate our customers on improving outcomes and recent publications. And we will leverage the final pending FDA confirmation letter." *Id.*

In response to these statements, analysts noted some concern over the slowdown, but expressed optimism that the growth rate would increase again. *See id.* ¶¶167–69. On May 23, 2019, Abiomed filed its quarterly report on Form 10-Q with the SEC, reporting the company's financial and operating results for its fourth fiscal quarter of 2019. *Id.* ¶ 170. Minogue and Trapp certified the filing. *Id.*

7. Subsequent FDA Letter

On May 21, 2019, the FDA issued an update regarding the Impella RP. *Id.* ¶ 62. In that letter, the FDA noted that, in the post-approval study, the survival rate of patients who would have qualified for the pre-market study was 64%, whereas the survival rate among patients who would not have qualified was less than 11%. *Id.* The letter also emphasized that, "when the device is used for the currently approved indication in appropriately selected patients[,] the benefits of the Impella RP continue to outweigh the risks." *Id.* Additionally, the FDA noted that it approved revised labeling for the Impella RP that included more information about which patients could benefit the most from treatment with the device. *Id.*

According to Local 705, both this letter and the February 4, 2019 letter from the FDA validated concerns related to Abiomed's ability to convince doctors to use Impella Pumps over IABPs. *Id.* ¶ 63.

8. Continued Slowdown and Final Disclosure Relating to the Class Period
On August 1, 2019, Abiomed issued a press release announcing its financial and
operating results for the first quarter of Fiscal Year 2020—which ended June 30, 2019.

Id. ¶ 172. In the press release, Abiomed disclosed its third consecutive quarter of slowing
revenue growth, reporting an increase of 15.4% year-over-year growth. Id. Commenting
on the disappointing financial results, Minogue stated that Abiomed's "new training
programs, organizational changes in distribution, and [] external initiatives . . . will
require time to drive more growth in the future." Id. ¶ 175. Relatedly, Abiomed
conceded that training physicians on "Impella access, closure and ICU management" was

the company's biggest obstacle among doctors not already using the Impella Pumps. *Id.* ¶ 173. Abiomed also revised down its guidance for Fiscal Year 2020, projecting an increase of only 15% to 20% over the prior year in total revenue, and projecting its operating margin to be in the range of 28% to 30%. *Id.* ¶ 175.

On this news, Abiomed's stock price fell \$73.69 per share, or 26.45%, to close at \$204.87 per share on August 1, 2019. *Id.* ¶ 176.

B. Additional Allegations

1. Confidential Witnesses

Local 705 relies on accounts from the following Abiomed employees:

- CW-1, who was a cardiology account manager at Abiomed on the west coast for the entire Class Period. *Id.* ¶ 68. CW-1 reported to a manager who reported to a region director who reported to Michael Howley, who was Vice President and General Manager of Global Sales at Abiomed. *Id.* ¶ 69.
- CW-2, who worked at Abiomed in numerous clinical roles from October 2014 until May 2020, and most recently served as a senior clinical consultant in Florida from April 2018 to May 2020. *Id.* ¶ 70.
- CW-3, who was a commercial training consultant at Abiomed from January 2017 to May 2019. *Id.* ¶ 71. CW-3 was responsible for aligning Abiomed's commercial initiatives with its sale progress and was brought in by Abiomed to launch commercial training processes for their sales methodology. *Id.*
- CW-4, who was a cardiology account manager in Miami, Florida for Abiomed from January 2019 to January 2020. *Id.* ¶ 72.
- CW-5, who was a clinical consultant on the east coast for Abiomed, from before the Class Period through the spring of 2019. *Id.* ¶73.
- CW-6, who was a logistics specialist and, before that, a production associate at Abiomed's headquarters. *Id.* ¶ 74. CW-6 worked for Abiomed from October 2017 to September 2019, and his responsibilities included warehouse and inventory management, which involved preparing periodic reports. *Id.*

• CW-7, who was a regional clinical manager at Abiomed from April 2019 to December 2019. *Id.* ¶ 75. In that role, CW-7 oversaw a clinical sales team that was responsible for Ohio, Indiana, and part of Kentucky. *Id.*

Local 705 categorizes allegations arising from these confidential witnesses' accounts into four topics: the sale of Impella Pumps; questions about clinical data and FDA reporting; market saturation; and meetings, calls, and reports.

a. Sales of Impella Pumps

Several of the confidential witnesses commented on Abiomed's sales practices. For instance, CW-2 stated that, when a hospital made its first Impella purchase, it was required to purchase a minimum of three Impella devices. *Id.* ¶ 76. Additionally, according to CW-1 and CW-2, Abiomed encouraged hospitals to have at least two Impella devices on hand. *Id.* In CW-2's view, this practice could damage Abiomed's relationships with the hospitals, as having devices that expire would not result in Medicare reimbursement. *Id.* ¶¶ 77–78. According to CW-2, some representatives lost accounts for this very reason. *Id.* ¶ 77.

According to some of these witnesses, sales representatives were very much aware of Abiomed's sales goals. According to CW-7, Abiomed's management discussed its 30% year-over-year growth figure "all the time," *id.* ¶ 79, and CW-1 emphasized that the sales goals were aggressive and unattainable, *id.* ¶ 80. CW-7 further stated that Abiomed's sales representatives felt pressured to sell "more than necessary" in light of those sales goals. *Id.* ¶ 79. CW-3 added that, because of the hours required to attempt to achieve these sales goals, there was high turnover among sales representatives. *Id.* ¶ 81.

Further, in light to its sales goals, Abiomed took efforts to increase its sales near the end of each quarter. For example, according to CW-1, at the end of each quarter, Abiomed pushed hospitals to submit a purchase order that could be charged upon shipment, so that the company could record the sale that quarter. *Id.* ¶ 82. Additionally, according to CW-2, sales representatives offered hospitals promotions that incentivized

purchases, such as providing a free console to a hospital that purchased two catheters. Id. ¶ 83. According to CW-2, hospitals were receptive to these incentives because they could earn reimbursements from insurers for some products in the bundle (e.g., catheters) while being unable to receive reimbursements for the other products that represented capital costs (e.g., consoles). Id.

b. Concerns About Clinical Data

CW-2 stated that the FDA's February 4, 2019 letter regarding increased mortality rates for the Impella RP led to only a small impact on sales, contrary to Abiomed's suggestion that the effect was more significant. *Id.* ¶ 84. CW-5 represented that he sold more Impella RP devices after that letter, noting that doctors were already using the devices for patients with very poor prognoses. *Id.* ¶ 97. In any event, CW-2 explained that the effect was mitigated when the FDA issued its follow-up letter on May 21, 2019. *Id.* ¶ 84.

CW-1 expressed concerns about Abiomed's data-sharing practices. According to CW-1, because Abiomed made most of its decisions in order to drive up its stock price, the company declined to provide doctors and hospitals research assistance if doing so cost the company money. *Id.* ¶ 85. Additionally, CW-1 recounted that only high-volume users were allowed to conduct the research they requested, and that Abiomed favored doctors who pushed Abiomed's "message" over other doctors who did not promote the company as much. *Id.*

Further, CW-1 stated that doctors questioned the efficacy of Abiomed's products and challenged the data collected regarding those products. *Id.* ¶ 86. CW-1 notes that some doctors believe the data Abiomed provided to the FDA may have been skewed. *Id.* ¶ 87. Moreover, according to CW-1, CW-3 and CW-4, many doctors were uncomfortable using Impella Pumps due to their view that, among other things, the products had high complication rates, high costs, and expiration dates that risked the products going unused.

Id. ¶¶ 88–91. CW-3 also noted that many doctors lacked the training to use Impella Pumps and already had training to help patients in other ways. *Id.* ¶ 91.

c. Market Saturation of Impella Pumps and Stalling Growth Rate

Multiple confidential witnesses noted that Abiomed emphasized its 30% growth rate, although witnesses differed as to whether that represented a yearly or quarterly figure. *See id.* ¶¶ 93 (CW-1, quarterly), 95 (CW-5, quarterly), 99 (CW-2, yearly). In any event, multiple confidential witnesses expressed that this growth goal was challenging and unsustainable, but Abiomed management—including Howley, specifically—put a lot of pressure on its sales representatives to attain these goals. *Id.* ¶¶ 93, 95–96, 99, 101, 107. According to CW-4, Abiomed also incentivized its employees to reach its sale goals by offering \$60,000 to \$70,000 in quarterly bonuses. *Id.* ¶ 101. Still, CW-4 noted that Abiomed would reach only one third of its sales goals quarter over quarter, based on his conversations with other sales representatives. *Id.*

Several of the confidential witnesses noted that Abiomed's growth slowed significantly at approximately the beginning of the Class Period and continued to slow down throughout it. *Id.* ¶¶ 99, 102, 104–06, 108. CW-3 noted that he conducted analyses to identify the causes of the declines in Abiomed's sales, concluding Abiomed needed more employees with sales experience. *Id.* ¶ 98. CW-2 added that, in approximately September 2018, Abiomed had maxed out all possible hospital clients who could purchase its devices. *Id.* ¶ 99 & n.25. In CW-2's view, the only way to continue the company's growth was to increase usage among existing clients, but some doctors were hesitant about increasing the use of Impella Pumps given their cost, their expiration dates, and prior negative experience with the devices. *Id.* ¶ 100. CW-4 offered a similar assessment about saturation in his territory and stalling sales from current clients, adding that doctors used Impella Pumps on only 10 to 15% of eligible patients but declined to do so because of health complications resulting from installation procedures and post-procedure management. *Id.* ¶¶ 102–03. CW-7 echoed this assessment, noting also that

doctors were looking for alternatives to Impella Pumps given their cost relative to IABPs. *Id.* ¶ 108. CW-7 represented that "new account numbers were fine," but device usage by current clients had stalled. *Id.* ¶¶ 109–10. CW-6, a logistics specialist, noted a decline in product shipments during this time period, and opined that the decrease in sales could have resulted from increased competition, low use by doctors, and poor engineering. *Id.* ¶ 106.

d. Meetings, Calls, and Reports

Employees at Abiomed regularly discussed sales figures. According to CW-1, Howley held monthly sales calls for all cardiology account managers, during which he presented information regarding device data and overall sales. Id. ¶ 112. CW-1 states that those figures were often inaccurate, but does not elaborate which figures were inaccurate or how they were inaccurate. See id. CW-7 also noted that he had weekly meetings to discuss sales numbers and device usage with his region, along with monthly conference calls with managers from all territories. Id. ¶ 113. Further, CW-4 noted that sales reports were generated and sent to all sales representatives on a daily basis, and those reports were also available to high-level executives. *Id.* ¶ 116. Additionally, several of the confidential witnesses highlighted that Abiomed had a system to track device usage, and that Abiomed leadership had access to this data as well. *Id.* ¶¶ 114–15, 117-18. And specifically, CW-7 emphasized that Minogue was "very hands on," "had access to everything we all had access to," and was "definitely very well-informed" as to the performance of the company. *Id.* ¶ 120–21. Additionally, CW-3 stated that Howley knew about each of Abiomed's accounts, doctors, and representatives and had "constant" meetings with Minogue. *Id.* ¶ 123.

According to many of these witnesses, sales and growth data were discussed regularly among leadership at Abiomed. According to CW-6, Abiomed also held "all-hands" meetings once a quarter during which the director of manufacturing talked about the decline in growth. *Id.* ¶ 119. CW-7 added that Minogue and Howley spoke at these

meetings. *Id.* Additionally, according to CW-3, discussions regarding sales growth occurred at Abiomed's monthly "all field" calls, in which Minogue and other senior leadership participated. *Id.* ¶ 122.

2. Stock Sales by Abiomed Executives During the Class Period

According to Local 705, Minogue and two non-parties—COO David Weber and Director Martin Sutter—sold stock during the Class Period in a suspicious manner. *Id.* ¶ 188. All three sold more stocks during the Class Period than during an equal length of time preceding the Class Period—*i.e.*, between February 2, 2017 and May 2, 2018 (the "Control Period"). *Id.* ¶¶ 190–91. Those sales and their proceeds are summarized in the tables below:

| | Shares Sold During Control Period | Shares Sold During Class Period |
|---------|--------------------------------------|------------------------------------|
|) (° | n enda | |
| Minogue | 0 | 105,000 |
| Weber | 59,000 | 89,782 |
| Sutter | 0 | 76,554 |

| | Proceeds During Control Period | Proceeds During Class Period |
|---------|-----------------------------------|---------------------------------|
| Minogue | 0 | \$46,166,898.68 |
| Weber | \$7,518,885.38 | \$35,896,662.31 |
| Sutter | 0 | \$26,437,568.00 |

Id. ¶ 191. Additionally, Minogue disposed of approximately 24.5% of his total shares that were available for sale during the Class Period, compared to 8.6% of shares that were available during the Control Period; Weber disposed of 50.1% of his total shares that were available for sale during the Class Period, compared to 40.1% that were available during the Control Period. Id. ¶¶ 193–94. According to Local 705, the timing of these

sales during the Class Period was suspicious because they occurred after Minogue, Weber, and Sutter learned about the deceleration of growth but before the public did *Id.* ¶¶ 199–202.

These sales, it should be noted, were made pursuant to Abiomed's Rule 10b5-1 Plans. Id. ¶ 205.

B. Procedural History

On August 6, 2019, Kyle Villare filed the instant suit. Doc. 1. On October 7, 2019, Joseph Barry filed a separate class action suit against the same defendants. *See Barry v. ABIOMED*, No. 19 Civ. 9258 (S.D.N.Y. 2019). On October 21, 2019, however, Barry filed a notice conceding that he did not have the largest financial interest in the instant matter. Doc. 30. In its June 29, 2020 Order, the Court appointed Local 705 as Lead Plaintiff and consolidated the two suits. Doc. 46.

On September 17, 2020, Local 705 filed its Amended Complaint. Doc. 52. On November 16, 2020, Defendants filed the instant motion. Doc. 56.

II. LEGAL STANDARD

A. Rule 12(b)(6)

To survive a motion to dismiss pursuant to Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). The plaintiff must allege sufficient facts to show "more than a sheer possibility that a defendant has acted unlawfully." *Id.* (citing *Twombly*, 550 U.S. at 556). However, this "flexible plausibility standard" is not a heightened pleading standard, *In re Elevator Antitrust Litig.*, 502 F.3d 47, 50 n.3 (2d Cir. 2007) (quotation omitted), and "a complaint."

. . does not need detailed factual allegations" to survive a motion to dismiss, *Twombly*, 550 U.S. at 555.

The question on a motion to dismiss "is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." Sikhs for Just. v. Nath, 893 F. Supp. 2d 598, 615 (S.D.N.Y 2012) (quoting Villager Pond, Inc. v. Town of Darien, 56 F.3d 375, 368 (2d Cir. 1995)). Indeed, "the purpose of Federal Rule of Civil Procedure 12(b)(6) is to test, in a streamlined fashion, the formal sufficiency of the plaintiff's statement of a claim for relief without resolving a contest regarding its substantive merits" or "weigh[ing] the evidence that might be offered to support it." Halebian v. Berv, 644 F.3d 122, 130 (2d Cir. 2011) (quotations omitted). Thus, when ruling on a motion to dismiss pursuant to Rule 12(b)(6), the Court accepts all factual allegations in the complaint as true and draws all reasonable inferences in the plaintiff's favor. Nielsen v. Rabin, 746 F.3d 58, 62 (2d Cir. 2014). In considering a Rule 12(b)(6) motion, a district court may also consider "documents attached to the complaint as exhibits[] and documents incorporated by reference in the complaint." Doe v. N.Y. Univ., No. 20 Civ. 1343 (GHW), 2021 WL 1226384, at *10 (S.D.N.Y. Mar. 31, 2021) (quotation mark omitted) (quoting DiFolco v. MSNBC Cable LLC, 622 F.3d 104, 111 (2d Cir. 2010)). "Judicial notice may be taken of documents that are 'integral to the complaint,' such that the complaint 'relies heavily upon [the documents'] terms and effect." Hesse, 463 F. Supp. 3d at 462 (quoting *Palin v. N.Y. Times Co.*, 940 F.3d 804, 811 (2d Cir. 2019)). Further, "[c]ourts have taken judicial notice of materials in the public record, such as federal copyright registrations, newspaper articles, and regulatory filings—all for the limited purpose of noting what the documents state, rather than to 'prove the truth of their contents." Id. (quoting Ace Arts, LLC v. Sony/ATV Music Pub., LLC, 56 F. Supp. 3d 436, 442 (S.D.N.Y. 2014)).

B. Rule 9(b)

A complaint alleging securities fraud must satisfy the heightened pleading requirements of Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act ("PSLRA") by stating the circumstances constituting fraud with particularity. See, e.g., ECA & Local 134 IBEW Joint Pension Tr. of Chi. v. JP Morgan Chase Co., 553 F.3d 187, 196 (2d Cir. 2009) (citing Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 320–21 (2007)). These requirements apply whenever a plaintiff alleges fraudulent conduct, regardless of whether fraudulent intent is an element of a claim. Rombach v. Chang, 355 F.3d 164, 170–71 (2d Cir. 2004) ("By its terms, Rule 9(b) applies to 'all averments of fraud." (quoting Fed. R. Civ. P. 9(b))).

Specifically, Rule 9(b) requires that a securities fraud claim based on misstatements must identify: (1) the allegedly fraudulent statements, (2) the speaker, (3) where and when the statements were made, and (4) why the statements were fraudulent. See, e.g., Anschutz Corp. v. Merrill Lynch & Co., Inc., 690 F.3d 98, 108 (2d Cir. 2012) (citing Rombach, 355 F.3d at 170). Conditions of a person's mind—such as malice, intent, or knowledge—may be alleged generally, however. Kalnit v. Eichler, 264 F.3d 131, 138 (2d Cir. 2001) (citing Fed. R. Civ. P. 9(b)). Like Rule 9(b), the PSLRA requires that securities fraud complaints "specify' each misleading statement," set forth the reasons or factual basis for the plaintiff's belief that the statement is misleading, and "state with particular facts giving rise to a strong inference that the defendant acted with the required state of mind." Dura Pharm., Inc. v. Broudo, 544 U.S. 336, 345 (2005) (quoting 15 U.S.C. §§ 78u-4(b)(1), (2)); see also, e.g., Slayton v. Am. Express Co., 604 F.3d 758, 766 (2d Cir. 2010).

These heightened pleading standards, when viewed together with the more general standards applicable to Rule 12(b)(6) motions to dismiss under *Twombly* and *Iqbal*, make clear that "plaintiffs must provide sufficient particularity in their allegations to support a plausible inference that is more likely than not that a securities law violation has been

committed." *In re Lululemon Sec. Litig.*, 14 F. Supp. 3d 553, 570 (S.D.N.Y. 2014), *aff'd*, 604 F. App'x 62 (2d Cir. 2015) (citing *ECA*, 553 F.3d at 196).

III. DISCUSSION

A. Section 10(b) and Rule 10b-5

Section 10(b) of the Exchange Act prohibits using or employing, "in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance," 15 U.S.C. § 78j(b) (1934), while Rule 10b-5 creates liability for a person who makes "any untrue statement of a material fact or . . . omit[s] to state a material fact . . . in connection with the purchase or sale of any security." *In re OSG Sec. Litig.*, 971 F. Supp. 2d 387, 397 (S.D.N.Y. 2013) (quoting 17 C.F.R. § 240.10b-5 (1951)). Rule 10b-5, promulgated by the SEC to implement section 10(b), "more specifically delineates what constitutes a manipulative or deceptive device or contrivance." *Press v. Chemical Inv. Servs. Corp.*, 166 F.3d 529, 534 (2d Cir. 1999). Under Rule 10b-5, it is unlawful for any person, directly or indirectly, by use of any means specified in section 10(b):

(a) To employ any device, scheme, or artifice to defraud, (b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5.

To state a private civil claim under section 10(b) and Rule 10b-5, a plaintiff must plead that: (1) the defendant made a material misrepresentation or omission, (2) with scienter, *i.e.*, a wrongful state of mind, (3) in connection with the purchase or sale of a security, and (4) that the plaintiff relied on the misrepresentation or omission, thereby (5) causing economic loss. *Dura*, 544 U.S. at 341–42; *see also Lattanzio v. Deloitte* &

Touche LLP, 476 F.3d 147, 153 (2d Cir. 2007). Defendants contest only the first two elements.

1. Material Misrepresentation or Omission

Defendants argue that Local 705 fails to state a claim for a violation of the Exchange Act, asserting it has not pled an actionable misstatement or omission.

Defendants also contend that the challenged statements constitute non-actionable corporate optimism or puffery, forward-looking statements, and opinion statements. The Court analyzes each of these arguments in turn.

a. Actionable Omissions

According to Local 705, Defendants made several false and misleading statements. Specifically, Local 705 contends that Defendants' statements regarding Abiomed's growth rate, its ability to grow sustainably and penetrate the market, and its execution of its five-year growth plan were all materially false and misleading.

According to Local 705, those statements were false and misleading because Defendants failed to disclose material adverse facts about Abiomed's business, including: Abiomed's stalling growth rate once it had reached a point where most hospitals ordering products were fully stocked and infrequently required reorders; the company's inability to convince doctors to regularly use Impella Pumps over other products, or to use the devices beyond their narrow indications; that Abiomed's revenue growth began to stall in May 2018 and worsened over the Class Period; Abiomed's unattainable growth expectations; and Abiomed's lack of a plan to stem the decline in revenue growth.

In other words, Local 705 relies on an omission theory to assert its Exchange Act claims. A "pure omission" is only "actionable under the securities laws [] when the corporation is subject to a duty to disclose the omitted facts." *Stratte-McClure v. Morgan Stanley*, 776 F.3d at 94, 101 (2d Cir. 2015). Nevertheless, "'pure omissions,' which are generally not actionable, differ from 'half truths,' or 'statements that are misleading under the second prong of Rule 10b-5 by virtue of what they omit to disclose.'" *In re Adient*

plc Securities Litigation, No. 18 Civ. 9116 (RA), 2020 WL 1644018, at *15 (S.D.N.Y. Apr. 2, 2020) (quoting *In re Viviendi*, 838 F.3d 223, 239–40 (2d Cir. 2016)). "The law is well settled that so-called 'half truths'—literally true statements that create a materially misleading impression—will support claims for securities fraud." *Id.* (quotation omitted). Still, "[w]hatever the scope of the responsibility not to make statements that constitute 'half truths,' that surely does not apply to the reporting of unmanipulated corporate earnings." *Boca Raton Firefighters and Police Pension Fund v. Bahash*, 506 F. App'x 32, 38 (2d Cir. 2012). Further, an alleged failure to acknowledge the long-term unsustainability of a business model does not, on its own, constitute actionable omission. *Id.*

Defendants emphasize that, at bottom, Local 705 seeks to hold them liable for failing to acknowledge the long-term unsustainability of Abiomed's business model, and that premise has been easily rejected in this Circuit. See id. Further, Defendants contend that Local 705 fails to plead with the requisite particularity that they omitted that the growth rate was assured to decline. Regarding this point, Defendants assert that Local 705 relies only on unsubstantiated innuendo from low-level confidential witnesses. According to Defendants, although some confidential witnesses reference a 30% salesgrowth goal, the Amended Complaint provides no further explanation regarding whether or how these goals were shared with the market, why they were unattainable, and when they became unattainable. Moreover, Defendants contend that Local 705's theory that growth was unsustainable because they had reached some maximum market penetration is contradicted by Abiomed's financial statements during the Class Period—statements that, Defendants note, Local 705 does not challenge. Further still, Defendants contend that, throughout the Class Period, they fully and consistently disclosed revenue growth, the number of sites Impella Pumps had and had not penetrated, the risks regarding doctor acceptance, and Abiomed's expectation that its revenue growth rate would decline.

Local 705 responds that it has sufficiently alleged a claim under an omissions theory. According to Local 705, Defendants' repeated statements that Abiomed was "positioned for sustainable growth" and that its "growth rates were in line with its 5-year vision outlined back in 2015" triggered a duty to tell the whole truth and disclose material facts necessary to make those statements not misleading. Local 705 further asserts that the confidential witnesses confirm that Abiomed could no longer achieve the market penetration necessary to grow sustainably. Thus, according to Local 705, it does not allege that Defendants' *generalized statements* about Abiomed's earnings generated a duty to disclose; instead, Local 705 alleges that Defendants' *affirmative statements* about Abiomed's growth required Defendants to disclose that such growth was not achievable, given the realities of the market for the Impella Pumps.

The Court agrees with Defendants. The analysis in *Adient*, 2020 WL 1644018 is instructive. In that case, the plaintiffs argued that the defendants "failed to disclose material information that was contemporaneously available to them at the time they made their statements, showing that [the Metals Division] was in fact struggling, not improving, and that its ability to contribute to [the company's] margin expansion goal was unreasonable and unrealistic." 2020 WL 1644018, at *15. The plaintiffs further argued that the defendants "knew, or had access to facts demonstrating, that ongoing inefficiencies, launch problems, personal/staffing problems, and other issues in [the Metals Division] made their statements about Metals' improvement and the main plan misleading." *Id.* The court concluded, however, that the plaintiffs failed to allege an actionable omission, noting that the accounts of the confidential witnesses in that case merely reflected the subjective views of how the company should have managed the alleged challenges, not that any of Defendants' statements were inaccurate at the time they were made or that any defendant believed those statements to be inaccurate when made. *Id.*

Likewise, Local 705 fails to allege an actionable omission here. Notably, Local 705 pleads no specific factual allegation indicating that future growth was assured to decline. Although the Amended Complaint offers the subjective views of confidential witnesses regarding the purported unsustainability of Abiomed's growth rates, those views are "not sufficient to demonstrate that any of [Defendants'] statements were inaccurate at the time they were made, or that any Defendant believed them to be so." *Id.* Moreover, during the Class Period, Defendants offered robust and specific disclosures that included detailed figures regarding market penetration and reorder rates, and informed investors in advance of risks and of a potential decline in growth rate. *See id.* (noting that the defendants publicly disclosed that, as issues arose in the metals division, the defendants began to examine the composition of projected margin expansion and explained that they would look to execute other measures to offset shortfalls). Because, in essence, Local 705 seeks to hold Defendants liable simply for failing to acknowledge the unsustainability of their business model, it has failed to allege an actionable omission. *See Boca Raton*, 506 F. App'x at 38.

b. Corporate Optimism or Puffery

Defendants also argue that, even if the challenged statements satisfy an omissions theory, they are still non-actionable corporate optimism or puffery. A statement of "puffery"—that is, "an optimistic statement that is so vague, broad, and non-specific that a reasonable investor would not rely on it"—"is not actionable." *Adient*, 2020 WL 1644018, at *21 (quoting *Galestan v. OneMain Holdings, Inc.*, 348 F. Supp. 3d 282, 297–98 (S.D.N.Y. 2018)); *see also Steamfitters Loc. 449 Pension Plan v. Skechers U.S.A., Inc.*, 412 F. Supp. 3d 353, 363 (S.D.N.Y. 2019), *aff'd sub nom. Cavalier Fundamental Growth Fund v. Skechers U.S.A., Inc.*, 826 F. App'x 111 (2d Cir. 2020) (summary order). Non-actionable statements include those "containing simple economic projections." *In re Express Scripts Holding Co. Sec. Litig.*, No. 16 Civ. 3338 (ER), 2017 WL 3278930, at *13 (S.D.N.Y. Aug. 1, 2017) (quoting *Novak v. Kasaks*, 216 F.3d 300, 315 (2d Cir.

2000)). "This rule permits companies 'to operate with a hopeful outlook,' because corporate officers 'are not required to take a gloomy, fearful or defeatist view of the future." *Galestan*, 348 F. Supp. 3d at 298 (quoting *Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004)). However, "statements regarding 'projections of future performance may be actionable . . . if they are worded as guarantees or are supported by specific statements of [then-existing] fact, . . . or if the speaker does not genuinely or reasonably believe them." *Adient*, 2020 WL 1644018, at *22 (quoting *In re Int'l Bus. Machs. Corp. Sec. Litig.*, 163 F.3d 102, 107 (1998)); *see also Galestan*, 348 F. Supp. 3d at 298. The critical inquiry in determining whether a statement constitutes puffery is "not whether the topic of a statement was a key to corporate success, but the nature of the specific statement and whether it concretely assured investors of anything." *Lopez v. Ctpartners Exec. Search Inc.*, 173 F. Supp. 3d 12, 29 (S.D.N.Y. 2016).

Defendants argue that Local 705 relies entirely on puffery, noting specifically that Local 705 challenges statements by Defendants that Abiomed was "well positioned" "to improv[e] clinical outcomes," "expand rapidly," "improv[e] operating margin"; to have "sustainable growth"; and to "continue to drive for best-in-class-performance," in line with its "goal . . . to remain one of the fastest-growing, most profitable med[-]tech companies in the market." According to Defendants, Local 705 essentially faults Defendants for remaining confident in their business and their short- to long-term outlook. But as Defendants note, the Second Circuit has repeatedly held that executives are not required to take a gloomy view of the future and, subject to what the current data indicate, they can be expected to be confident about the prospects of their company. Moreover, Defendants emphasize that statements containing simple economic projections and expressions of optimism are insufficient to support a securities fraud complaint. Here, according to Defendants, the challenged statements fall precisely into this category of non-actionable statements given their general and broad commentary about Abiomed's future performance.

Local 705 responds that Defendants cherry pick statements out of context to support their arguments. According to Local 705, when viewed in context, Defendants' statements are not mere rosy predictions but are instead concrete misrepresentations of then-existing facts. Thus, according to Local 705, those statements are not mere puffery because they are determinate, verifiable statements.

Regarding this argument, Local 705 cites two examples. First, Local 705 argues that, while "sustainable growth" may by itself constitute puffery, it is rendered a verifiable statement when read in the following context: "we're also maintaining the best in growth rate at a higher base and we're doing it while improving operating margin. So again, it's sustainable growth." Doc. 52. ¶ 126. According to Local 705, when read in context, the statement "it's sustainable growth" refers to the words that precede it—including that Abiomed was maintaining its growth rate and improving its operating margin. Second, Local 705 emphasizes that the statement that Abiomed's "business continues to expand rapidly" must be read with the rest of the sentence: "and our growth rates are in line with our 5-year vision outlined back in 2015." *Id.* ¶ 127. Local 705 asserts that this statement is also verifiable, as Abiomed's growth rates either are or are not in line with what the company outlined in 2015. Thus, according to Local 705, the challenged statements represent more than simple economic projections or expressions of optimism; rather, they are actionable, concrete misrepresentations of fact.

The Court agrees with Defendants. Contrary to Local 705's position, the challenged statements, and the context in which they were made, are indistinguishable from statements other courts in this District have deemed to be puffery. For example, in *Adient*, the court concluded that several challenged statements were "too general for a reasonable investor to have relied on them." 2020 WL 1644018, at *22. Those statements included ones in which the defendants stated that the company had seen "a big improvement in [M]etals"—one of the divisions in the company—and "a little bit of improvement on the metals side." *Id.* Additionally, one defendant had stated that the

metals division was "on [the] upwards trajectory." *Id.* The court concluded that those "statements, and others like them, did not reference specific improvements in Metals that were actually false at the time or could have misled a reasonable investor, and [the plaintiffs] ha[d] failed to show that such statements were concrete, specific statements of fact." *Id.* More specifically, the court noted that the plaintiffs had not alleged specific contradictory facts that would have rendered false the general statements about improvements of the company's metals department or progress within the company. *Id.* And as the court noted, although the metals division "may have been important to [the defendants'] success," the "[d]efendants' statements about improvements in Metals were not sufficiently specific or concrete to mislead reasonable investors." *Id.*

Similarly, the court found that statements concerning the expected "turnaround" in the metals division constituted non-actionable puffery. For example, the defendants stated: "[W]e expect a combination of improved operating performance and lower capital expenditures to drive significantly higher cash generation." *Id.* at *23. The plaintiffs alleged that that such statements "continued to mislead the market by falsely reassuring investors that a strategic review of the [Metals] division and new management in [Metals] was rapidly stabilizing the business and driving near-term improvements." *Id.* Nevertheless, the court concluded that these statements amounted to puffery, as they "detail[ed] the defendants' expectations and hopes for the company, in light of the disclosed operations challenges." *Id.*

Steamfitters is also instructive. In that case, the plaintiffs challenged the following statements:

- "Based on the reaction by key accounts during our interim meetings this month in our corporate offices, we believe the strength of our brand and our product has not slowed."
- "We believe we are well positioned to maintain this growth."

- "[W]hen you grow at the pace we were growing and the demand keeps growing, you don't really have inventory issues. . . . The good news is we're growing at a faster pace than even our consumers around the world anticipate order [sic] for. I don't think it's changed very much."
- "[W]e continue to be at the top end of where, we think we should be. And sell-throughs continue and acceptance continues, and we haven't seen any slowdown."
- "I think it's fair to say that those names you mentioned, like DSW and Shoe Carnival, our business grows, and if it wasn't growing there, it'll be very difficult for us to maintain the growth we've shown domestically."
- "The present has never looked as . . . successful thanks to our product and marketing, and resulting record sales, shipments, and earnings."

Steamfitters, 412 F. Supp. 3d at 363–65. The court concluded that, because these statements lacked "sufficient specificity to offer any guarantee of some concrete fact or outcome," they constituted non-actionable puffery. *See id.* at 363.

The court in *In re Aratana Therapeutics Inc. Sec. Litig.*, 315 F. Supp. 3d 737 (S.D.N.Y. 2018) also concluded that statements like the ones at issue constituted puffery. These statements included that the company had "made remarkable progress towards our stated goals of advancing our expanding pipeline towards commercialization," that the company was "confident about and prepared for what lays ahead," that the company was "proud" to be "on track to have these products reach the market in 2016," and that the company was "confident in these products and our overall commercialization strategy." *Aratana*, 315 F. Supp. 3d at 757–58. According to the court, these were "broad assertions" that simply put a "positive spin on developments in the [FDA approval] process" and, therefore, were non-actionable. *Id*.

Finally, the statements in *Schaffer v. Horizon Pharma PLC*, No. 16 Civ. 1763 (JMF), 2018 WL 481883 (S.D.N.Y. Jan. 18, 2018) are especially on point. In that case, the court concluded that several challenged statements were textbook cases of puffery.

Id. at *9. That court emphasized that statements by the defendants "extolling their 'unique commercial business model," "noting that the company was 'on track," and "highlighting that prescription growth was 'exceeding [their] expectations' were not actionable under the securities laws." Id. As the court concluded, "[p]ut simply, these statements—and the many others like them in the Amended Complaint"—were "too general to cause a reasonable investor to rely upon them." Id. (quoting City of Westland Police & Fire Ret. Sys. v. MetLife, Inc., 129 F. Supp. 3d 48, 77 (S.D.N.Y. 2015)).

As in those cases, here the challenged statements are too vague and generic to be actionable. Moreover, Local 705 fails to demonstrate any concrete guarantee or baseline by which to verify the challenged statements, see Steamfitters, 412 F. Supp. 3d at 363, unlike cases in which courts have concluded that statements were verifiable and, therefore, actionable, see, e.g., City of Warren Police & Fire Ret. Sys. v. World Wrestling Entm't Inc., 477 F. Supp. 3d 123, 129 (S.D.N.Y. 2020) (verifiable statement where company said it had been "working on the rights renewal process" in the Middle East but rights had been terminated); see also In re Avon Sec. Litig., No. 19 Civ. 1420 (CM), 2019 WL 6115349, at *8 (S.D.N.Y. Nov. 18, 2019) (verifiable statement where company said bad debt expenses were "fully cleared up and booked in the 2016 results" when they were not). Although Local 705 attempts to label the challenged statements as verifiable ones, Local 705 fails to meaningfully distinguish the challenged statements in the instant suit from the broad statements that other courts have concluded were puffery. Accordingly, Abiomed's growth and expansion "may have been important to [Abiomed's] success, but Defendants' statements about" Abiomed's growth and expansion "were not sufficiently specific or concrete to mislead reasonable investors." Adient, 2020 WL 1644018, at *22.

Local 705 also points to a few cases where courts in this District have concluded that repeated representations that would ordinarily constitute puffery could give rise to liability under section 10(b). *See Avon*, 2019 WL 6115349, at *16; *see also In re Petrobras Sec. Litig.*, 116 F. Supp. 3d 368, 381 (S.D.N.Y. 2015). In particular, Local 705

asserts that, in line with those cases, Defendants' repeated use of the phrase "sustainable growth" should render the challenged statements actionable. But contrary to Local 705's position, the repetition of puffery does not, by itself, render it actionable. Rather, as the courts in those cases emphasize, the context in which statements were made matters, and a court must determine whether a reasonable investor could rely on those statements as reflective of the true state of affairs at the company. *See, e.g., Petrobras*, 116 F. Supp. 3d at 381. And again, when contextualized, the challenged statements are simply too generic for a reasonable investor to rely on. Accordingly, the Court concludes that Defendants' challenged statements constitute non-actionable puffery.

c. Forward-looking Statements

Defendants argue that the challenged statements would also be protected under the PSLRA's safe harbor for forward-looking statements. The PSLRA defines a forward-looking statement as one that contains, among other things, "a projection of revenues, income, [or] earnings," "plans and objectives of management for future operations," or "a statement of future economic performance." 15 U.S.C. § 78u-5(i)(1); see also In re Gen. Elec. Co. Sec. Litig., 857 F. Supp. 2d 367, 384–85 (S.D.N.Y. 2012) ("The PSLRA defines forward-looking statements to include, inter alia, . . . statements of the plans and objectives of management for future operations . . . and statements of future economic performance." (internal citations and quotations omitted)), reconsideration granted in part, 856 F. Supp. 2d 645 (S.D.N.Y. 2012). Forward-looking language need not be contained in a separate section or be specifically labeled. See Francisco v. Abengoa, S.A., 481 F. Supp. 3d 179, 210 (S.D.N.Y. 2020). Rather, "the facts and circumstances of the language used in a particular report will determine whether a statement is adequately identified" as forward looking. Slayton v. Am. Express Co., 604 F.3d 758, 769 (2d Cir. 2010).

More specifically, a forward-looking statement is not actionable if (1) it is identified and accompanied by meaningful cautionary language, (2) it is immaterial, or

(3) the plaintiff fails to prove that the statement was made with actual knowledge that it was false or misleading. *See Aratana*, 315 F. Supp. 3d at 755 (citing *Slayton*, 604 F.3d at 766). "Because the statute is written in the disjunctive, statements are protected by the safe harbor if they satisfy any one of these three categories." *Id*.

According to Defendants, the challenged statements regarding potential growth are quintessentially forward-looking statements protected under the PSLA's safe harbor, as they are about Abiomed's growth goal. Additionally, Defendants contend that the statements about the company being on track with respect to that goal also constitute forward-looking statements, and note several cases in this District reaching the same conclusion about analogous language. *See, e.g., Steamfitters*, 412 F. Supp. 3d at 362.

In response, Local 705 argues that most of the challenged statements are not forward looking at all. Instead, the statements are based on representations of historical or contemporaneous facts—and therefore, are not protected by the PSLRA's safe harbor. Local 705 notes that several statements contain present-tense elements, such as:

- "And we're also maintaining this best in growth rate at a higher base and we're doing it while improving operating margin. So again, it's sustainable growth, it's strategic, but we have to improve outcomes."
- "[O]ur growth rates are in line with our 5-year vision outlined back in 2015."
- "Abiomed is positioned for sustainable growth."

Doc. 61 at 15 (quoting Doc. 52 ¶¶ 126, 127, 146).³ According to Local 705, these statements reflected Abiomed's then-current ability to grow sustainably—not a projection that it will. Local 705 therefore argues that the safe-harbor provision does not apply.

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³ Local 705 notes several other examples, but the above-quoted statements are representative of the challenged statements. *See* Doc. 61 at 15 n.10.

Local 705 is correct that "'[w]here a statement contains references to both future and past or present conditions, safe harbor protection may only extend to the prognostic portion,' but 'context is everything.'" Steamfitters, 412 F. Supp. 3d at 363 (quoting Gissin v. Endres, 739 F. Supp. 2d 488, 505-06 (S.D.N.Y. 2010)). Accordingly, "[t]he safe harbor provision still applies where 'defendants are not making guarantees about the present,' but are instead 'stating their educated guess about what the preceding quarter's financial data would mean for the company's future." Id. (alterations omitted) (quoting Gissin, 739 F. Supp.2d at 506). Moreover, "when the present-tense portion of mixed present and future statements does not provide specific information about the current situation, but merely says that, whatever the present situation is, it makes the future projection attainable, the present-tense portion of the statement is too vague to be actionable apart from the future projection." In re Supercom Inc. Sec. Litig, No. 15 Civ. 9650 (PGG), 2018 WL 4926442, at *21 (S.D.N.Y. Oct. 10, 2018) (quotation omitted). Thus, where "[t]he alleged misstatements contain some present-tense language, but are all forward-looking as a whole," they are protected by the PSLRA's safe harbor provision. Steamfitters, 412 F. Supp. 3d at 363; see also In re Anheuser-Busch InBev SA/NV Sec. Litig., No. 19 Civ. 5854 (AKH), 2020 WL 5819558, at *4 (S.D.N.Y. Sept. 29, 2020).

The Court concludes that the present-tense portions of the challenged statements, when examined in context, fail to make any contemporaneous guarantee, simply stating educated guesses about what the preceding financial data would mean for Abiomed's future; accordingly, both the forward-looking and present-tense portions of those statements are covered by the PSRLA's safe harbor provision. Moreover, Local 705's attempt at casting Abiomed's statements about growth as present-tense statements—*i.e.*, that such statements are about Abiomed's *then-current* ability to grow sustainability rather than about projections that the company will grow—is unpersuasive. By Local 705's logic, a statement that a company "will grow" is protected under the safe harbor provision, while a statement that a company "thinks it will grow" is not. Such a

distinction would be meaningless, especially because a company's current ability to grow is necessarily implicit in every future projection. *See Supercom*, 2018 WL 4926442, at *21.

The Court also notes that several other courts in this District have examined similar language and concluded that such statements are forward looking. For example, in *Anheuser-Busch*, the court reviewed alleged misstatements that, in one form or another, stated that the company was "tracking in line with [its] internal deleveraging targets' and that it 'continue[d] to expect dividends to be a growing flow over time, although growth in the short term is expected to be modest." 2020 WL 5819558, at *4. Those statements "of projected performance and dividends, even mixed with statements about current progress, [were] forward-looking statements." *Id*.

Steamfitters is also instructive. In that case, the court examined the following statements that contained present-tense or contemporaneous portions:

- "Having just achieved a new annual sales record of \$2.4 billion in 2014, we expect[] the momentum to continue into 2015."
- "The demand for Skechers footwear in markets worldwide continues, and . . . [w]e believe that our accelerated growth trend will remain through 2015 and into 2016."
- "With increased year-over-year backlogs at the end of June, strong incoming order rates and July sales, as well as the positive sell-through reports from wholesale . . . we believe that we will continue to achieve new sales and profit records through 2015. . . . [W]e believe we are well prepared for our planned growth."

Steamfitters, 412 F. Supp. 3d at 362, 365. The court concluded that, although the statements contained some present-tense portions, the statements were forward looking as a whole and, therefore protected under the safe harbor provision. *Id.* at 363.

And consistent with the analysis in those cases, other courts in this District have held that language stating that a company was presently on track with its projected goals was forward looking under the PSLRA. *See Adient*, 2020 WL 1644018, at *19 ("Even statements about [the company] being 'on track' with respect to its projected margin expansion are 'forward-looking' statements within the meaning of the PSLRA."); *see also Aratana*, 315 F. Supp. at 758 (concluding that statements that "[W]e believe that we are on track to have these products reach the market in 2016. . . . We very much look forward to launching these products next year" and "We believe we have or will have sufficient supply of formulated drugs to meet our commercial forecast" were forward-looking statements). Accordingly, the Court concludes that the challenged statements are, on the whole, forward-looking statements subject to the protection of the safe harbor provision.

From there, the Court must determine whether the forward-looking statements are protected because they (1) were made without actual knowledge, (2) were immaterial, *or* (3) were accompanied by cautionary language.

Regarding actual knowledge, "[t]he scienter requirement for forward-looking statements—actual knowledge—is stricter than for statements of current fact. Whereas liability for the latter requires a showing of either knowing falsity or recklessness, liability for the former attaches only upon proof of knowing falsity, pled with the required particularity." *Aratana*, 315 F. Supp. 3d at 756 (quotation and citation omitted).

Defendants argue that Local 705 has failed to satisfy this burden, asserting that it has failed to plead that each challenged forward-looking statement was made or approved with actual knowledge of its falsity. At most, according to Defendants, Local 705 repeats in a conclusory fashion that Defendants "knew or recklessly" disregarded the deceleration in revenue growth. Local 705 responds with just one footnote, stating that, should the Court conclude that the challenged statements are forward looking,

Defendants made those statements "with actual knowledge of their falsity." Doc. 61 at 20

n.15. Because Local 705 fails to meaningfully contest Defendants' arguments in its opposition, the Court concludes that Local 705 concedes the issue of actual knowledge. *See Abengoa*, 481 F. Supp. 3d at 211 n.9; *see also Carbon Inv. Partners, LLC v. Bressler*, No. 20 Civ. 3617 (ER), 2021 WL 3913526, at *9 (S.D.N.Y. Sept. 1, 2021). And in any event, the Court agrees with Defendants that Local 705 has failed to plead actual knowledge of the falsity of each challenged statement with the requisite particularity, as it has simply alleged in a conclusory fashion that Defendants had actual knowledge of those statements.⁴ *See Adient*, 2020 WL 1644018, at *20; *Aratana*, 315 F. Supp. 3d at 756.

Defendants also argue that, even if Local 705 sufficiently pleaded actual knowledge, the challenged statements were accompanied by cautionary language that affords those statements protection under the safe harbor provision. The PSLRA's safe harbor provision provides that no liability attaches to certain forward-looking statements that are identified as such and are "accompanied by meaningful cautionary language identifying important factors that could cause actual results to differ materially from those in the forward looking statements." Francisco v. Abengoa, S.A., 481 F. Supp. 3d 179, 210 (S.D.N.Y. 2020) (quoting In re Nokia Oyj (Nokia Corp.) Sec. Litig, 423 F. Supp. 2d 364, 400 (S.D.N.Y. 2006)); see also 15 US.C. § 78u-5(c)(1)(A)(i). "To avail themselves of safe harbor protection under the meaningful cautionary language prong, defendants must demonstrate that their cautionary language was not boilerplate and conveyed substantive information." Abengoa, 481 F. Supp. 3d at 210. In other words, "[t]o qualify as 'meaningful,' cautionary language 'must convey substantive information about factors that realistically could cause results to differ materially from those projected in the forward-looking statements." Aratana, 315 F. Supp. 3d at 755 (quoting Slayton, 604 F.3d at 771). "To determine whether cautionary language is meaningful, courts must first

⁴ Moreover, to the extent that Local 705 relies on the allegations referenced in its argument in support of scienter, the Court concludes that Local 705 fails to allege actual knowledge for the same reasons it concludes that Local 705 fails to allege scienter. *See infra*, Section II.B.2.

'identify the allegedly undisclosed risk' and then 'read the allegedly fraudulent materials—including the cautionary language—to determine if a reasonable investor could have been misled into thinking that the risk that materialized and resulted in his loss did not actually exist." *In re Delcath Sys., Inc. Sec. Litig.*, 36 F. Supp. 3d 320, 333 (S.D.N.Y. 2014) (quoting *Halperin v. eBanker USA.com, Inc.*, 295 F.3d 352, 359 (2d Cir. 2002)). A plaintiff "may establish that cautionary language is not meaningful 'by showing, for example, that the cautionary language did not expressly warn of or did not directly relate to the risk that brought about [the plaintiff's] loss." *Aratana*, 315 F. Supp. 3d at 756 (quoting *Halperin*, 295 F.3d at 359).

Defendants emphasize that, in each of its reports and releases that contained the challenged statements, they expressly warned investors regarding "risks and uncertainties." *See, e.g.*, Doc. 58-12 at 3 (transcript of earnings call for second quarter of Fiscal Year 2019). Defendants also cautioned investors "not to place considerable reliance on any forward-looking statements." *See, e.g.*, August 2, 2018 10-Q Statement, *available at*

https://www.sec.gov/Archives/edgar/data/0000815094/000156459018018814/abmd-10q_20180630.htm ("August 2, 2018 10-Q Statement"). Further, Defendants note that every press release, earnings call, and quarterly filing during the Class Period referred investors to risks detailed in Abiomed's annual reports, which stated that Abiomed's "ability to generate revenues from [its] Impella devices may be impaired by the" following factors:

our failure to obtain approvals from the FDA and foreign regulatory authorities to comply with government regulations[;]...lack of acceptance or continued acceptance by physicians; ... the availability of other products and procedures that are technically equivalent or superior to our products, and which may be sold at lower prices; product performance and design; sales, marketing and distribution capabilities; comparable clinical outcomes; ... hospital

acceptance of our products; penetration into existing and new geographic markets.

See May 24, 2018 10-K Statement, available at

https://www.sec.gov/Archives/edgar/data/0000815094/000156459018014310/abmd-10k_20180331.htm; see also e.g., August 2, 2018 10-Q Statement (stating several of the same risk factors). According to Defendants, this cautionary language warned of the very risks on which Local 705 bases this action—namely, that Abiomed's actual results could materially differ from its projected results because of competition from IABP and challenges in convincing and training medical providers to adopt the Impella Pumps.

In response, Local 705 argues that Defendants' cautionary language is boilerplate and generic—and thus not sufficiently meaningful to satisfy the PSLRA. Of course, a defendant's failure to update cautionary language over time to reflect new information and new risks would render such statements boilerplate, and therefore forward-looking statements accompanied by such language would not necessarily be protected under the safe harbor provision. *See Slayton*, 604 F.3d at 772–73. However, Local 705 cites "no authority for the proposition that cautionary language must change where the standard risks the company faces stay the same." *Steamfitters*, 412 F. Supp. 3d at 363. Here, the cautionary language warns of the very risks that Local 705 alleges that Defendants failed to disclose, and according to Local 705's own allegations, those risks were present throughout the Class Period. *See Aratana*, 315 F. Supp. 3d at 755. Accordingly, the Court concludes that the challenged statements are forward-looking statements subject to the safe harbor provision of the PSLRA and, therefore, are not actionable.⁵

d. Non-actionable Opinions

⁵ As noted, a forward-looking statement is also not actionable if it is immaterial. *See Aratana*, 315 F. Supp. 3d at 755. For the reasons stated above, the Court also concludes that the challenged statements are immaterial. *See infra*, Section II.A.1.a.

Defendants also argue that the statements at issue are non-actionable opinions. "A 'sincere statement of pure opinion is not an untrue statement of material fact, regardless of whether an investor can ultimately prove the belief wrong." *Steamfitters*, 412 F. Supp. 3d at 364 (quoting *Omnicare*, *Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 186 (2015)). "Expressions of optimism and projections about the future are quintessential opinion statements." *Id.* (quoting *Martin v. Quartermain*, 732 F. App'x 37, 40 n.1 (2d Cir. 2018) (summary order)). An opinion statement, however, may give rise to liability under section 10(b) in two distinct ways. *See Lopez*, 173 F. Supp. 3d at 23.

First, "liability for making a false statement of opinion may lie if either 'the speaker did not hold the belief [he] professed' or 'the supporting fact[s] [he] supplied were untrue." *Tongue v. Sanofi*, 816 F.3d 199, 210 (2d Cir. 2016) (quoting *Omnicare*, 575 U.S. at 185–86). However, "a sincere statement of pure opinion is not an 'untrue statement of material fact,' regardless [of] whether an investor can ultimately prove the belief wrong." *Omnicare*, 575 U.S. at 186. "As the Second Circuit 'has firmly rejected the fraud by hindsight approach[,]' it is 'not sufficient for these purposes to allege that an opinion was unreasonable, irrational, excessively optimistic, [or] not borne out by subsequent events." *Adient*, 2020 WL 1644018, at *15 (quoting *Lopez*, 173 F. Supp. 3d at 24); *see also Aratana*, 315 F. Supp. 3d at 754.

Second, "opinions, though sincerely held and otherwise true as a matter of fact, may nonetheless be actionable if the speaker omits information whose omission makes the statement misleading to a reasonable investor." *Sanofi*, 816 F.3d at 210. "A reasonable investor 'expects not just that the [speaker] believes the opinion (however irrationally), but that it fairly aligns with the information in the [speaker's] possession at the time." *Adient*, 2020 WL 1644018, at *16 (quoting *Omnicare*, 575 U.S. at 188–89). "To adequately allege that a statement of opinion was misleading through the omission of material information, '[t]he investor must identify particular (and material) facts going to

the basis for the issuer's opinion—facts about the inquiry the issuer did or did not conduct or the knowledge it did or did not have—whose omission makes the opinion statement at issue misleading to a reasonable person reading the statement fairly and in context." *Aratana*, 315 F. Supp. 3d at 755 (quoting *Sanofi*, 815 F.3d at 209). "The core inquiry" therefore "is whether the omitted facts would 'conflict with what a reasonable investor would take from the statement itself." *Sanofi*, 815 F.3d at 210 (quoting *Omnicare*, 575 U.S. at 189).

However, the Supreme Court has "cautioned against an overly expansive reading of this standard, noting that '[r]easonable investors understand that opinions sometimes rest on a weighing of competing facts,' and adding that '[a] reasonable investor does not expect that every fact known to an issuer supports its opinion statement." *Id.* (quoting *Omnicare*, 575 U.S. at 189–90). Accordingly, "a statement of opinion 'is not necessarily misleading when an issuer knows, but fails to disclose, some facts cutting the other way." *Id.* (quoting *Omnicare*, 575 U.S. at 189). Moreover, the Supreme Court has emphasized that "statements of opinions must be considered in the context in which they arise." *Aratana*, 315 F. Supp. 3d at 755. "[T]he investor takes into account the customs and practices of the relevant industry,' and . . . 'an omission that renders misleading a statement of opinion when viewed in a vacuum may not do so once that statement is considered, as is appropriate, in a broader frame." *Sanofi*, 816 F.3d at 210 (quoting *Omnicare*, 575 U.S. at 190).

Defendants argue that the challenged statements are statements of opinion, as they are focused on predictions of future performance, which are inherently statements of goals or beliefs. Local 705 argues that, when viewed in context, most are statements of fact. But as Defendants note, Local 705 does not challenge the accuracy of Abiomed's historic growth rate; rather, at bottom, Local 705 challenges "statements of goals or beliefs" regarding "continued progress" towards "sustainable growth" and meeting a long-term vision. *Adient*, 2020 WL 1644018, at *17 (concluding that such statements

constituted non-actionable opinion statements). Courts in this District routinely hold that such statements—even if implicating some factual component—constitute opinion statements because, when contextualized, those statements are "expectations about the future rather than presently existing, objective facts." *See Aratana*, 315 F. Supp. 3d at 758 (quotation omitted); *see also Adient*, 2020 WL 1644018, at *8, *17; *Steamfitters*, 412 F. Supp. 3d at 364 (concluding that the following was an opinion: "I think it's just more of the same. . . . We continue to grow in the U.S. by category expansion, shelf expansion, price point expansion. So I don't think anything changes significantly other than we continue to grow at a significant pace."); *Supercom*, 2018 WL 4926442, at *23 (concluding that the following was an opinion: "We [we]re very close to hav[ing] a large contract awarded in November [or] December, which we believe was just delay, and we believe that [we] should be [] confident in the user in just 90 days."). Accordingly, the Court concludes that the challenged statements also constitute statements of opinion.

From there, the Court must determine whether Local 705 satisfies either basis for establishing liability for opinion statements. First, Defendants assert that Local 705 fails to establish that Defendants did not subjectively believe the opinions at the time they were made. Although briefly asserting that Defendants' opinion statements are actionable because, at least in part, Defendants did not genuinely hold the expressed opinions, Local 705 also states that it "does not need to establish that Defendants did not believe their stated opinions for those statements to be actionable." Doc. 61 at 18–19. Instead, Local 705 asserts that it has satisfied the second basis for liability of opinion statements. *See id.* Accordingly, the Court concludes that Local 705 has conceded the issue. But in any event, the Court agrees with Defendants. Notably, there are no specific allegations regarding Defendants' beliefs at the time the alleged statements were made. At most, Local 705 relies on the beliefs and opinions of confidential witnesses. However, none of the confidential witnesses "is alleged to be the 'maker' of any of the alleged misstatements, and it is the facts known to, and the intent of, the maker of the statements

which is ultimately relevant when the Court considers the falsity of statements of belief opinion." *In re Lululemon Sec. Litig.*, 14 F. Supp. 3d 553, 580 (S.D.N.Y. 2014).

Second, Defendants argue that Local 705 fails to plead that Defendants omitted information whose omission makes their statements misleading to a reasonable investor. Regarding this point, Local 705 reiterates its arguments in support of its position that it pleads an actionable omission. *See* Doc. 61 at 19.

The Court agrees with Defendants. "The existence of financial challenges, particularly where Defendants had acknowledged these challenges and outlined efforts to mitigate them, does not render Defendants' optimistic opinion statements actionable." *Anheuser-Busch*, 2020 WL 5819558, at *6 (citing *Omnicare*, 575 U.S. at 189). As discussed, Defendants both disclosed all relevant financial data and, in every SEC filing, acknowledged the very risks to the growth rate that Local 705 identifies in the Amended Complaint. And in any event, Local 705's case "essentially boils down to an allegation that [Defendants'] statements were misleading for failure to include a fact that would have potentially undermined Defendants' optimistic projections," but "Defendants were only tasked with making statements that 'fairly align[ed] with the information in the issuer's possession at the time." *Sanofi*, 816 F.3d at 212 (quoting *Omnicare*, 575 U.S. at 189) (noting that defendants need not have disclosed FDA feedback simply because it tended to cut against their projections). Accordingly, the Court concludes that Local 705 has failed to allege a material misrepresentation or omission to support a claim under section 10(b).

2. Scienter

Defendants also argue that Local 705 has failed to adequately plead scienter. A plaintiff may establish scienter by alleging facts that either (1) show that the defendant had both the "motive and opportunity" to commit the alleged fraud, or (2) constitute "strong circumstantial evidence of conscious misbehavior or recklessness." *ECA*, 553 F.3d at 198. The relevant inquiry for the Court "is whether *all* of the facts alleged, taken

collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets the standard." *In re Magnum Hunter Res. Corp. Sec. Litig.*, 26 F. Supp. 3d 278, 291–92 (S.D.N.Y. 2014), *aff'd*, 616 F. App'x 442 (2d Cir. 2015) (citing *Tellabs*, 551 U.S. at 322–23); *see also ECA*, 553 F.3d at 198; *Medis Inv'r Grp. v. Medis Tech., Ltd.*, 586 F. Supp. 2d 136, 141 (S.D.N.Y. 2008) ("In order to determine whether a complaint has adequately pleaded scienter, a court should examine all of the facts alleged collectively or 'holistically' (without parsing individual allegations), and take into account any inference concerning scienter—supporting or opposing—which can be drawn from the complaint."), *aff'd*, 328 F. App'x 754 (2d Cir. 2009) (summary order). "According to the Supreme Court, the critical inquiry is: 'When the allegations are accepted as true and taken collectively, would a reasonable person deem the inference of scienter at least as strong as any opposing inference?" If so, then scienter has been adequately pleaded. If not, the case may be dismissed." *Medis*, 586 F. Supp. 2d at 141 (citing *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 326 (2007)).

First, Defendants argue that Local 705 fails to allege that they acted with motive and opportunity. "A complaint has sufficiently alleged 'motive and opportunity to commit fraud' if it pleads facts showing that the defendant 'benefited in some concrete and personal way from the purported fraud." *Van Dongen v. CNinsure Inc.*, 951 F. Supp. 2d 457, 468 (S.D.N.Y. 2013) (quoting *Novak*, 216 F.3d at 307–08). While "[t]he opportunity to commit fraud is generally assumed where the defendant is a corporation or corporate officer," *id.* (collecting cases), general motives common to most corporate officers do not constitute "motive" for the purpose of establishing scienter. *ECA*, 553 F.3d at 198. Therefore, the desire for the corporation to appear profitable and the desire to keep stock prices high to increase officer compensation do not suffice to establish a motive. *See Abengoa*, 481 F. Supp. 3d at 213; *see also Van Dongen*, 951 F. Supp. 2d at 468 (citing *Novak*, 216 F.3d at 307).

Local 705 argues that the stock trades by Minogue and other Abiomed insiders during the Class Period establish motive. Motive can be established "when corporate insiders allegedly make a misrepresentation in order to sell their own shares at a profit." *In re Citigroup Inc. Sec. Litig.*, 753 F. Supp. 2d 206, 233 (S.D.N.Y. 2010). Nevertheless, the mere fact that insider stock sales occurred is not sufficient to establish scienter; instead, a plaintiff must establish that the sales were unusual or suspicious. *In re Gildan Activewear, Inc. Sec. Litig.*, 636 F. Supp. 2d 261, 270 (S.D.N.Y. 2009). To determine whether trading is unusual or suspicious, a court examines the following factors:

(1) the amount of net profits realized from the sales; (2) the percentages of holdings sold; (3) the change in volume of insider defendant's sales; (4) the number of insider defendants selling; (5) whether sales occurred soon after statements defendants are alleged to have known were misleading; (6) whether sales occurred shortly before corrective disclosures or materialization of the alleged risk; and (7) whether sales were made pursuant to trading plans such as Rule 10b5-1 plans.

Nguyen v. New Link Genetics Corp., 297 F. Supp. 3d 472, 493 (S.D.N.Y. 2018). The plaintiff bears the burden of establishing that the defendants' stock sales are unusual or suspicious. *Id.* (citing *Acito v. IMCERA Grp.*, 47 F.3d 47, 54 (2d Cir. 1995)).

Here, the Amended Complaint acknowledges that those trades were made pursuant to Rule 10b5-1 plans. Doc. 52 ¶ 205; see also Doc. 58-15. It is well established that, ordinarily, trades pursuant to 10b5-1 plans do not raise a strong inference of scienter. Glaser v. The9, Ltd., 772 F. Supp. 2d 573, 592 (S.D.N.Y. 2011). "Although this axiom does not apply where a 10b5-1 plan is entered into or strategically amended to take advantage of an inflated stock price or insider information," the Amended Complaint here "contains no such allegations" beyond conclusory ones. Koplyay v. Cirrus Logic, Inc., No. 13 Civ. 790 (CM), 2013 WL 6233908, at *6 (S.D.N.Y. Dec. 2, 2013); see also Nguyen, 297 F. Supp. 3d at 494 (noting that 10b5-1 trading plans are not defenses to

allegations when entered into during class period). Local 705 avers that it is unclear when the 10b5-1 plans were entered into, and therefore that Defendants have failed to establish that the plan was entered into before they acquired insider information during the Class Period. But of course, Local 705 has it exactly backwards: it is Local 705 that bears the burden of pleading allegations to establish that the stock sales are unusual or suspicious. *Nguyen*, 297 F. Supp. 3d at 493. Moreover, as to Minogue, even if he "realized some proceeds (and profit) from stock sales during the Class Period, his holdings . . . actually *increased* during that period." *Glaser*, 772 F. Supp. 2d at 592; *see also* Docs. 58-16 and 58-17. Considering these facts, the Court concludes that Local 705 has failed to allege that the stock sales were suspicious or unusual. And because Local 705 asserts no other basis upon which to establish motive, the Court finds that it has failed establish scienter through the motive-and-opportunity theory.

Where, as here, a plaintiff fails to allege a motive to commit fraud, the plaintiff's allegations that indicate a defendant's conscious misbehavior or recklessness "must be correspondingly greater." *Kalnitt*, 264 F.3d at 142 (internal quotation marks and citation omitted); *see also Abengoa*, 481 F. Supp. 3d at 213. In order to establish scienter under the conscious misbehavior or recklessness theory, a plaintiff "must show conduct by defendants that is at least highly unreasonable and which represents an extreme departure from the standards of ordinary care to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it." *In re Initial Pub. Offering Sec. Litig.*, 358 F. Supp. 189, 216 (S.D.N.Y. 2004) (internal quotation marks omitted) (quoting *Kalnitt*, 264 F.3d at 142); *see also Abengoa*, 481 F. Supp. 3d at 213. To the extent that plaintiffs assert that defendants had access to contrary facts, the complaint must "specifically identify the reports or statements containing that information." *In re Gen. Elec. Co. Sec. Litig.*, 856 F. Supp. 2d 645, 659 (S.D.N.Y. 2012) (citation omitted). "Recklessness in the scienter context[, however,] cannot be merely enhanced negligence." *In re JP Morgan Chase Sec. Litig.*, 363 F. Supp. 2d 595, 624 (S.D.N.Y.

2005); *Medis Inv'r Grp.*, 586 F. Supp. 2d at 142 ("To properly allege recklessness, the plaintiff must plead 'a state of mind approximating actual intent, and not merely a heightened form of negligence.""). Moreover,

[u]nlike statements about historical facts, in which the scienter inquiry focuses on whether the defendants 'knew facts or had access to information suggesting that their public statements were not accurate' or 'failed to check information they had a duty to monitor,' the recklessness inquiry as to forward-looking projections focuses on whether the defendants knew at the time they made these projections that they were unrealistic or unlikely to come true.

City of Austin Police Ret. Sys. v. Kinross Gold Corp., 957 F. Supp. 2d 277, 301 (S.D.N.Y. 2013) (citing ECA, 553 F.3d at 199; then citing, Podany v. Robertson Stephens, Inc., 318 F. Supp. 2d 146, 153–54 (S.D.N.Y. 2004)).

Defendants argue that Local 705 fails to sufficiently allege conscious misbehavior or recklessness. According to Defendants, none of the confidential witnesses asserts direct knowledge of what Minogue and Trapp were specifically aware of, much less that they were aware of specific contrary facts when they made their statements. Rather, Defendants note, those witnesses emphasize only that Minogue and Trapp had access to reports, that sales of devices were tracked, that Abiomed leadership was able to access device data, and that senior executives were very hands on. Defendants contend that such generic allegations fail to give rise to a strong inference of scienter. Further, Defendants assert that neither Minogue's and Trapp's high-level positions nor the importance of the Impella Pumps to Abiomed, by themselves, is sufficient to establish scienter.

In response, Local 705 argues that the allegations from the confidential witnesses establish scienter, as the confidential witnesses place Minogue and Trapp in pertinent meetings and establish that they had access to specific information contradicting their public statements. Additionally, Local 705 notes that Howley also attended and spoke at

several of those meetings and knew all of Abiomed's sale data; and although not as high level as Minogue and Trapp, he directed sales goals for the company and held regular calls, thereby allowing his knowledge to be imputed to Abiomed. Moreover, according to Local 705, those allegations place Abiomed's management in specific and particular meetings during which the company's downward trajectory was discussed. Local 705 emphasizes that those meetings, coupled with Defendants' access to troubling data about Abiomed's sales growth and the fact that the Impella Pumps represented almost all of Defendants' revenue, establish scienter.

The Court agrees with Defendants. As an initial matter, the Court concludes that Howley's scienter cannot be imputed to Abiomed. Whether an employee's "scienter can be imputed to [the company] depends on whether [she] was a sufficiently senior officer at the company." *Barrett v. PJT Partners Inc.*, No. 16 Civ. 2841 (VEC), 2017 WL 3995606, at *7 (S.D.N.Y. Sept. 8, 2017). "[I]n making this determination, the Court should consider the individual's relatively seniority at the issuing entity and the connection between the executive's role and the fraudulent statements." *Id.* Although Howley spoke at internal meetings regarding sales performance, was familiar with data relating to sales growth, and set internal sales goals, those allegations do not reflect that he had any role in the formulation of sales projections that were disclosed to the public. *Id.* at *8.

Moreover, Howley was not alleged to be a senior manager, cutting against imputing his knowledge to Abiomed. *See id.*

Further, even assuming that the Court could rely on all of the confidential witness statements, those accounts are insufficient to support a strong inference of scienter. As discussed, those accounts largely reflect the subjective assessments of the confidential witnesses themselves—not the mental states of Minogue and Trapp. Although Abiomed's executives attended meetings and were generally aware of growth and strategy, Local 705 still fails to allege specific facts giving rise to an inference that Defendants consciously disregard that future growth would inevitably decline.

Local 705's argument that Minogue and Trapp's management style and access to information support a strong inference of scienter is also unavailing. In essence, Local 705 relies on the fact the Minogue and Trapp were hands-on and had access to extensive raw data—and thus must have been apprised of the problems related to market penetration and growth that Abiomed was experiencing during the Class Period. See Maloney v. Ollie's Bargain Outlet Holdings, Inc., 518 F. Supp. 3d 772, 781 (S.D.N.Y. Feb. 10, 2021). However, "simply alleging that executive defendants are 'closely involved' in running their business is not enough to show that they had access to contrary information." City of N. Miami Beach Police Officers' and Firefighters' Ret. Plan v. Nat'l Gen. Holdings Corp., No. 19 Civ. 10825 (JPO), 2021 WL 212337, at *10 (S.D.N.Y. Jan. 21, 2021). "Although evidence of a hands-on management style may support an inference of scienter in some cases, it is insufficient to establish scienter on its own." *Maloney*, 518 F. Supp. 3d at 781. Moreover, simply asserting that executives had access to extensive raw data that reflected problems in Abiomed's growth rate is insufficient to raise an inference of scienter. See City of N. Miami, 2021 WL 212337, at *10. Again, scienter requires that a defendant be specifically informed of contrary information. Id. at *8, 10–11.

Local 705 also relies, in part, on the "core operations" doctrine to establish scienter, asserting that Defendants must have been aware of slowing sales growth and issues with market penetration for the Impella Pumps given that the devices made up 96% of Abiomed's revenue. Under that doctrine, "if a plaintiff can plead that a defendant made false or misleading statements when contradictory facts of critical importance to the company either were apparent, or should have been apparent, an inference arises that high-level officers and directors had knowledge of those facts by virtue of their positions with the company." *In re Atlas Air Worldwide Holdings, Inc. Sec. Litig.*, 324 F. Supp. 2d 474, 489 (S.D.N.Y. 2004); *see also Schwab v. E*TRADE Fin. Corp.*, 258 F. Supp. 3d 418, 434 (S.D.N.Y. 2017). "In other words, this doctrine allows courts to draw an inference of

about their core operations." *City of Omaha Police & Fire Ret. Sys. v. Evoqua Water Techs. Corp.*, 450 F. Supp. 3d 379, 423 (S.D.N.Y. 2020). The Second Circuit has not expressly determined if the "core operations" doctrine remains applicable to provide scienter after the enactment of the PSLRA. *See Frederick v. Mechel OAO*, 475 F. App'x 353, 356 & n.5 (2d Cir. 2012) (summary order). However, the Second Circuit has suggested that the doctrine can provide additional support for an inference of scienter, even if it cannot establish scienter on its own. *See City of Omaha*, 450 F. Supp. 3d at 424. The majority of courts in this Circuit—including this one—have adopted this approach. *See id.* (collecting cases); *see also In re Kandi Techs. Grp., Inc. Sec. Litig*, No. 17 Civ. 1944 (ER), 2019 WL 4918649, at *7–8 (S.D.N.Y. Oct. 4, 2019). Moreover, in deciding whether to apply the core operations doctrine, courts in this District have required that the operation at issue make up nearly all of a company's business or be essential to its survival. *See Kandi*, 2019 WL 4918649, at *7.

Although the Impella Pumps represent a sufficient portion of Abiomed's business to satisfy the core operations doctrine, *see id.*, the Court finds Local 705's allegations insufficient, on the basis of that doctrine alone, to establish scienter on behalf of Defendants, *see Maloney*, 518 F. Supp. 3d at 781. Indeed, while the importance of the Impella Pumps should have strengthened Defendants' awareness of any specific contradictory fact or information, that import cannot not substitute for specific factual allegations linking Defendants to the alleged fraud. *See Kandi*, 2019 WL 4918649, at *8; *see also Schwab*, 258 F. Supp. 3d at 434.

Of course, in determining whether Local 705 has adequately established scienter, "[t]he Court is mindful of its obligation to consider 'whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *City of N. Miami*, 2021 WL 212337, at *11 (quoting *Tellabs*, 551 U.S. at 323). But Local 705's allegations fall short

both individually and collectively. *See Tellabs*, 551 U.S. at 314. Accordingly, the Court concludes that Local 705 has failed to state a claim pursuant to section 10(b).

C. Section 20(a)

Local 705 brings a claim for violation of section 20(a) against Minogue and Trapp. Section 20(a) of the Exchange Act imposes liability on individuals who control any person or entity that violates section 10. *See* 15 U.S.C. 78t(a). "To assert a *prima facie* case under Section 20(a), a plaintiff 'must show a primary violation by the controlled person and control of the primary violator by the targeted defendant, and show that the controlling person was in some meaningful sense a culpable participant in the fraud perpetrated by the controlled person." *Bd. of Trs. of City of Ft. Lauderdale Gen. Emps. 'Ret. Sys. v. Mechel OAO*, 811 F. Supp. 2d 853, 882 (S.D.N.Y. 2011) (quoting *S.E.C. v. First Jersey Sec., Inc.*, 101 F.3d 1450, 1472 (2d Cir. 1996)), *aff'd sub nom. Frederick v. Mechel OAO*, 475 F. App'x 353 (2d Cir. 2012) (summary order). Because Local 705 has failed to allege a primary violation of the Exchange Act, its claim pursuant to section 20(a) is also dismissed. *See Steamfitters*, 412 F. Supp. 3d at 369.

IV. CONCLUSION

For the foregoing reasons, Defendants' motion is GRANTED. Because Local 705 has requested leave to amend its complaint, and amendment would not necessarily be futile, Local 705 is granted leave to move to amend in accordance with the following schedule: Local 705 shall file its motion by October 12, 2021, Defendants shall file their opposition by November 2, 2021, and Local 705 shall file its reply shall by November 9, 2021. The Clerk of Court is respectfully directed to terminate the motion, Doc. 56, and the requests for oral argument are denied as moot, Docs. 62 and 66.

It is SO ORDERED.

Dated:

September 21, 2021 New York, New York

EDGARDO RAMOS, U.S.D.J.